

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Samuel J. Shuster et al. Art Unit : 1635  
Serial No. : 10/537,741 Examiner : Kimberly Chong  
Filed : April 24, 2006 Conf. No. : 3556  
Title : METHODS AND MATERIALS FOR MODULATING TRPM2

**Mail Stop Amendment**

Commissioner for Patents  
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**RESPONSE TO RESTRICTION REQUIREMENT**

Responsive to the Restriction Requirement mailed November 16, 2007, Applicants elect the invention of Group I, claims 1-8, 12 and 15-17. Regarding the Examiner's requirement for a further election, Applicants provide the following comments.

On page 2 of the current Restriction Requirement, the Examiner equates accessible region of nucleotides 2821-2838 with SEQ ID NO:3, nucleotides 3879-3896 with SEQ ID NO:4, nucleotides 4276-4294 with SEQ ID NO:5 and nucleotides 5661-5678 with SEQ ID NO:6. The Examiner also asserted that “[c]laims 1, 9 and 12 specifically claims antisense oligonucleotides as listed, which are targeted to a TRPM2 gene.”

For clarification purposes, Applicants respectfully submit that the Examiner's interpretation of the claims as well as the sequence identifiers that the Examiner assigned to the accessible regions are incorrect. For example, the accessible regions called out in claim 1 refer to *a region* to which an antisense oligonucleotide of 10-50 nucleotides in length binds.

*Representative* oligonucleotides that bind to these regions are shown in Table 1 and recited in claim 12; SEQ ID NO:6 corresponds to nucleotides 2821-2838, SEQ ID NO:4 corresponds to nucleotides 3879-3896, SEQ ID NO:3 corresponds to nucleotides 4276-4294, and SEQ ID NO:5 corresponds to nucleotides 5661-5678. The antisense oligonucleotides of claim 1, however, are not limited to these particular sequences. In other words, each of the antisense oligonucleotides recited in claim 12 is a species of each genus of antisense oligonucleotides that specifically hybridizes to one of the accessible regions recited in claim 1 (or claim 9).

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The Examiner indicated that Applicants are required to elect one antisense sequence from claims 1, 9, or 12. Based on the explanation provided herein, it is not entirely clear as to a suitable election. Accordingly, Applicants elect the accessible region defined by nucleotides 2821 through 2838 of SEQ ID NO:1 in claim 1. If the Examiner requires election of a particular species of antisense oligonucleotides that specifically hybridizes to this accessible region, then Applicants elect the antisense oligonucleotide of claim 12 having the sequence of SEQ ID NO:6. It is noted that claims 1-8, 12, and 15-17 read on Applicants' election.

Applicants respectfully traverse this lack of unity rejection.

First, the U.S. Patent & Trademark Office, acting as the International Search Authority, did not deem the accessible regions recited in claim 1 to lack unity during the International Phase of the PCT application from which the instant National Phase application claims benefit. That is, the US/ISA searched "the first sequence listed in the claims, SEQ ID NO:1" in issuing the International Search Report. According to MPEP §1893.03(d), the same unity of invention practice is applicable in National Phase applications submitted under 35 U.S.C. §371 as that applied to international applications.

In addition, Applicants respectfully submit that further restriction of Group I down to one particular accessible region or even one particular antisense oligonucleotide is improper. The antisense oligonucleotides encompassed by the claims and delineated by their ability to specifically hybridize to one of the indicated accessible regions comply with the guidelines set forth in the PCT Administrative Instructions at Annex B, Section (f). Contrary to the Examiner's assertion that each antisense sequence behaves in a different way, the claimed oligonucleotides meet the criteria of (A) because all alternatives (i.e., each antisense molecule that specifically hybridizes to an accessible region) not only have a common activity (i.e., inhibiting the production of TRPM2), they also have the common property of binding to regions of a common sequence (human TRPM2; SEQ ID NO:1). Also contrary to the Examiner's assertion that the claimed antisense oligonucleotides do not comply with the requirements of unity of invention, the instant oligonucleotides do meet the criteria of (B)(2) because all alternatives belong to the same art recognized class of compounds (i.e., antisense oligonucleotides), and each member could be substituted one for the other with the expectation that the same intended result would be achieved (i.e., inhibiting the production of TRPM2). Thus, according to the guidelines set forth

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in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 has been met.

Applicants submit that the further restriction of the claims of Group I is improper, and respectfully request that the further restriction of Group I be withdrawn and that SEQ ID NO:1 be evaluated with respect to all of the recited accessible regions.

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

/March 24, 2008/

/M. Angela Parsons/

Date: \_\_\_\_\_

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